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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,083	12/28/2001	Richard A. Terwilliger	WORLD-01000US1 SRM	3945

23910 7590 01/15/2003

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EXAMINER

CADUGAN, JOSEPH A

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,083

Applicant(s)

TERWILLIGER ET AL.

Examiner

Joseph A. Cadugan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-91 is/are pending in the application.
- 4a) Of the above claim(s) 26,27,29-33,42-48,55-64,72 and 77-91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25,28,34-41,49-54,65-71 and 73-76 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-25, 28, 49-54, 65-71, and 73-76, drawn to a therapeutic radiation element, classified in class 600, subclass 7.
 - II. Claims 26-27 and 77-78, drawn to a therapeutic element for drug or hormone delivery, classified in class 604, subclass 19.
 - III. Claims 29-33, 42-48, 64, and 72, drawn to a brachytherapy device, classified in class 600, subclass 3.
 - IV. Claims 55-63 and 79-91, drawn to a prescription method for treating tissue, classified in class 600, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are used for completely different applications, as group II is for delivery of a drug or hormone, and group I is for radiation therapy in the body, and their effects are clearly different.
3. Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the brachytherapy device fails to claim the radioactive seed elements dispersed in the elongate member, or the use of drug or hormone delivery. The subcombination has separate utility such as in use of non-brachytherapy radiation treatment or for the storage and transport of radiation sources.
4. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed

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can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the steps of creating or selecting a treatment plan as claimed are not necessary to use the device, and the process as claimed does not require the elongate member as claimed or the dispersal of the seeds as claimed, and could be done with a hollow wire or catheter instead.

5. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are used for completely different applications, as group II is for delivery of a drug or hormone, and group III is for brachytherapy, and their effects are clearly different.

6. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are used for completely different applications, as group II is for delivery of a drug or hormone, and group IV is planning radiation therapy, and their effects are clearly different.

7. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the brachytherapy device of group III need not have the planning steps of group IV, and the steps of the method don't require the brachytherapy device claimed including the needles and plugs and stylets.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. During a telephone conversation with Sheldon Meyer on 10 January 2003 a provisional election was made without traverse to prosecute the invention of group 1, claims 1-25, 28, 49-54, 65-71, and 73-

76. Affirmation of this election must be made by applicant in replying to this Office action. Claims 26-27,

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29-48, 55-64, 72, and 77-91 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-25, 28, 49-54, 65-71, and 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox (USP 6,159,143) in view of Candelaria et al. (USP 6,497,646). Lennox teaches a method and device for delivery of therapeutic agents in conjunction with isotope seed placement. Lennox teaches a device for brachytherapy where the radioactive seeds (22) and spacers (24) are held in a continuous elongate member (See Figure 2). Lennox teaches that ¹⁰³Pd, ¹⁹⁸Au, ¹²⁵I, and ¹⁹²Ir are used in brachytherapy (col. 1, Ins. 20-25) and that a short half-life and low energy is desired (col. 1, Ins. 33-34). The spacers can contain a therapeutic hormone or drug, and that an outer layer can be biodegradable to allow release of a therapeutic drug or hormone (col. 4, Ins. 33-40).

Lennox fails to teach that the seed contains the drug or hormone and is bio-absorbable. However, it would have been obvious to one of ordinary skill in the art to put the therapeutic agent of the spacer in the seed, as this would involve a simple combination of claimed elements. It has been held obvious to one having ordinary skill in the art at the time the invention was made to put the drug or hormone in the seed, since it has been held that integrating into one piece articles which have formerly

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been separate involves only routine skill in the art. Further, the seeds would have to be bio-absorbable to release the drug or hormone, as the spacers are.

Lennox also does not teach making the solid member thick enough to deter normal tissue necrosis. However, Lennox teaches that normal tissue necrosis is undesirable (col. 1, Ins. 29-33), and making the wall of a catheter or other radiation delivery device thicker to provide some shielding is notoriously well known in the art, and would have been obvious to one of ordinary skill in the art at the time of the invention.

Although Lennox teaches that the device should be made of a bio-absorbable polymer, but does not name the polymer (col. 3, Ins. 29-32), the exact number of days over which the bio-absorbable or bio-degradable elements will degrade, the use of an echogenic material, the durometer range, steam sterilizability, or the use of air bubbles. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the device of Lennox of any known bio-absorbable polymer or to make it echogenic or give it air bubbles or any other desirable characteristic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Lennox fails to teach that the device is axially stiff but radially flexible. Candelaria teaches a radiotherapy source ribbon having variable radiotherapy. There are seeds (106) that are spaced (108) as needed and held in a solid, elongate member (102) that is flexible enough to pass through a tortuous passage but axially stiff enough to push through said passages (col. 5, Ins. 35-38). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the radially flexible and axially stiff ribbon of Candelaria with the radiation therapy device of Lennox, as this would allow the device to pass through tortuous passages without jamming or collapsing as explained above.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Liprie (USP 5,833,593) teaches a flexible source wire for irradiation. Keren (USP 6,283,911) teaches a radiation seed with a throughbore. Von Hoffmann (USP 6,312,374) teaches a radioactive wire placement

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catheter. Ildstad et al. (USP 6,039,684) teaches a treatment using radiation and hormones or drugs for AIDS. Mavity et al. (USP 6,248,057) teach an absorbable brachytherapy and chemotherapy delivery device and method. Langton et al. (USP 5,460,592) teach an apparatus and method for carrying seeds having dual shells. Coniglione (USP 5,713,828) teaches a hollow-tube brachytherapy device.

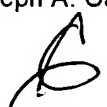
Contact Information

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph A. Cadugan whose telephone number is (703) 305-0879. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached at (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Joseph A. Cadugan


January 10, 2003


MAX F. HINDENBURG
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